



NDA 20-184/S-009

Solvay Pharmaceuticals, Inc.
Attention: Ms. Leslie Owtrim
60 Columbia Way, Suite 102
Markham, Ontario
L3R OC9
Canada

Dear Ms. Owtrim:

Please refer to your supplemental new drug application dated May 5, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aceon® (perindopril erbumine) 2, 4, and 8 mg Tablets.

We also acknowledge receipt of your submission dated July 18, 2003.

This "Changes Being Effected" supplemental new drug application provides for changes to the **WARNINGS** section of labeling as follows:

1. Under **WARNINGS**, the **Angioedema** subsection was re-titled "**Head and Neck Angioedema**".
2. Following the **Head and Neck Angioedema** subsection and before the paragraph entitled "In large U.S. postmarketing study..." the following text has been added:

Intestinal Angioedema: Intestinal angioedema has been reported in patients treated with ACE inhibitors. These patients presented with abdominal pain (with or without nausea or vomiting); in some cases there was no prior history of facial angioedema and C-1 esterase levels were normal. The angioedema was diagnosed by procedures including abdominal CT scan or ultrasound, or at surgery, and symptoms resolved after stopping the ACE inhibitor. Intestinal angioedema should be included in the differential diagnosis of patients on ACE inhibitors presenting with abdominal pain.

In addition, we note the following revisions:

1. Under the INDICATIONS AND USAGE section, "**Head and Neck**" has been added at the end of the last paragraph for reference.
2. Under PRECAUTIONS, Hyperkalemia subsection, "**See PRECAUTIONS:**" has been added at the end of the paragraph for reference.
3. The following text has been added at the end of the package insert:
Manufactured by:
Patheon Pharmaceuticals, Inc.
Cincinnati, OH 45215-6300

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) dated on July 18, 2003.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Alisea Sermon, Pharm.D.
Regulatory Project Manager
(301) 594-5334

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Doug Throckmorton
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